

**Notice of Allowability**

Application No.

10/516,587

Examiner

Malgorzata A. Walicka

Applicant(s)

NISHI ET AL.

Art Unit

1652

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/11/06.
2. ☒ The allowed claim(s) is/are 3,4,9,11,12,17-20,24-34 and 36-39.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date See Continuation Sheet
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 05/09/05, initialed the last position.

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The Amendment of October 11, 2006 is acknowledged. Claims 7, 10, 15, 23 and 35 have been cancelled by the current amendment. Claims 1, 2, 5, 6, 8, 13, 14, 16, 21 and 22 have been previously cancelled. Claims 3, 11, 19, 28, 29-33, 36 and 39 have been amended. Claims 3-4, 9, 11-12, 17-20, 24-34, 36-39 are pending and under examination.

### **DETAILED ACTION**

#### **1. Priority**

Acknowledgment is made of applicants' claim for priority based on an application number 2002-165722 filed in Japan on 06/06/2002. Applicants filed the priority document, however it is not translated. SEQ ID NO: 1 and 2 are disclosed in the priority document, as well as are drawings presenting data for wild type acylase set forth by SEQ ID NO: 2. The Japanese application does not seem to disclose mutated SEQ ID NO: 2 and effects of mutation, which are only shown in PCT/JP03/06807. In result claims 4, 5, 6, 7, 11-19, 21, 22, 25-38 are entitled only to the priority date of filing of the PCT/JP03/06807 application, which is May 30, 2003.

#### **2. Objections**

Claims 3 and 15 were objected in the final Office Action of July 11, 2006 (final action).

Objection to claim 15 is moot because the claim has been cancelled. Objection to claim 3 was improper because the claim did not recite the objected phrase.

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Objections to claims 31-32 are withdrawn, because the claims have been amended.

### **3. Rejections**

#### **3.1. 35 USC section 101**

Rejection of claim 28 made in the final action is withdrawn, because the claim have been amended.

#### **3.2. 5 USC, section 112, second paragraph**

Claims 3, 11, 19 and 23 were rejected in the final action for reciting the phrase "not less than 90% in total". Rejection of claim 23 is moot because the claim has been cancelled. Rejection of claim 3, 11, 19 is withdrawn because the claims have been amended.

Rejection of claims 28, 36 and 39 is also withdrawn because the claims have been amended.

#### **3.3. 35 USC, section 112, first paragraph**

##### **3.3.1. Lack of written description**

Rejection of claims 7, 10, 15 and 23 made in the final action is moot, because the claims have been cancelled.

##### **3.3.2. Scope of enablement**

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Claims 3, 7, 9, 11, 18, 19, 24, 25, 27, 29, 30, 33, 34, 36, 37. and 39 were finally rejected.

The rejection is moot in case of claim 7, which is cancelled, and rejection of the rest of the claims is withdrawn, because the claims have been amended.

#### **4. Examiner's amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Please amend claim 3, 4, 11, 12, 19, 20, 24, 25, 26, 34, 36, 37 and 39 as follows.

3. An isolated and purified gene which contains a DNA encoding [coding for] a protein comprising the [an] amino acid sequence shown under SEQ ID NO: 2.

4. An isolated and purified gene which contains a DNA encoding [coding for] a protein comprising the [an] amino acid sequence shown under SEQ ID NO: 2, in which the 204<sup>th</sup> methionine in the amino acid sequence shown under SEQ ID NO: 2 is substituted with valine.

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11. An isolated and purified polynucleotide which contains a nucleotide sequence encoding [coding for] a protein consisting of the [comprising an] amino acid sequence shown under SEQ ID NO: 2.

12. An isolated and purified polynucleotide which contains a nucleotide sequence encoding [coding for] a protein consisting of the [comprising an] amino acid sequence shown under SEQ ID NO: 2, in which the 204<sup>th</sup> methionine in the amino acid sequence shown under SEQ ID NO: 2 is substituted with valine.

19. An isolated and purified protein which comprises the [an] amino acid sequence shown under SEQ ID NO: 2.

20. An isolated and purified protein which comprises the [an] amino acid sequence shown under SEQ ID NO: 2, in which the 204<sup>th</sup> methionine in the amino acid sequence shown under SEQ ID NO: 2 is substituted with valine.

24. An isolated and purified gene which contains a transcription regulatory sequence contained in the gene according to Claim 3, wherein the transcription regulatory sequence is a sequence containing the 100 nucleotides upstream [100 bases upstream site] from the 125<sup>th</sup> residue in SEQ ID NO: 1.

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25. An isolated and purified gene which contains a translation regulatory sequence contained in the gene according to Claim 3, wherein the translation regulatory sequence is a sequence containing the 50 nucleotides upstream [50 bases upstream site] from the 125<sup>th</sup> residue in SEQ ID NO: 1.

26. The gene according to Claim 3 under the control of [regulon containing] a transcription and/or translation regulatory sequence, wherein either or both of said transcription and/or translation regulatory sequence(s) is (are) substituted with other transcription and/or translation regulatory sequence from the same or different living organism.

34. An isolated and purified  $\beta$ -lactam acylase which comprises an amino acid sequence encoded [coded] by the polynucleotide according to Claim 11.

36. A method of producing a  $\beta$ -lactam acylase in a transformed microorganism or of enhancing the production

which comprises preparing the recombinant vector according to Claim 27, transforming a host microorganism with said recombinant vector, culturing [cloning] the obtained transformed microorganism, and isolating said  $\beta$ -lactam acylase [selecting it].

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37. A method of producing a  $\beta$ -lactam antibiotic by bringing a  $\beta$ -lactam core substrate and a side chain substrate into contact with [using] the  $\beta$ -lactam acylase according to Claim 34.

39. An immobilized  $\beta$ -lactam acylase which is obtained by culturing the transformed microorganism according to Claim 28, and immobilizing the [a]  $\beta$ -lactam acylase extracted and/or purified from the transformed microorganism.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative, Steven S. Yu, on October 24, 2006.

## 5. Allowance

Claims 3- 4, 9, 11-12, 17-20, 24-34 and 36-39 are allowed for reasons explained in the Office action of Feb. 7, 2006.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00



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a.m. to 4:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner

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